

S/N 09/991,522

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	Jeffrey E. Stahmann et al.	Examiner:	Kristen Droesch
Serial No.:	09/991,522	Group Art Unit:	3762
Filed:	November 20, 2001	Docket No.:	279.400US1
Title:	TRIGGERED STORAGE OF DIAGNOSTIC DATA ASSOCIATED WITH COMPROMISED RESYNCHRONIZATION THERAPY		

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**AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111**

MS Amendment  
Commissioner for Patents  
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Alexandria, VA 22313-1450

This responds to the Office Action mailed on July 15, 2004. Please amend the above-identified patent application as follows.

### IN THE CLAIMS

Please amend the claims as follows:

1. (Currently Amended) A cardiac rhythm management device, comprising:
  - a plurality of sensing channels, each such channel comprising an electrode connected to a sense amplifier for sensing cardiac electrical activity;
  - a plurality of pacing channels, each such channel comprising an electrode connected to a pulse generator for delivering pacing pulses to a heart chamber;
  - a controller for controlling the delivery of pacing pulses and for receiving data from the sensing channels;
  - wherein the controller is programmed to:
    - pace both ventricles in accordance with a ventricular resynchronization pacing mode;
  - and,
  - store data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating ~~degradation of resynchronization therapy~~ a decrease in pacing frequency over a specified period of time.
2. (Original) The device of claim 1 wherein the stored data is an electrogram from the selected sensing channel.
3. (Original) The device of claim 1 wherein the stored data is marker/interval data reflecting sensing and pacing events in the selected sensing channel and time intervals therebetween.
4. (Original) The device of claim 1 wherein the triggering condition is when the percent of paced cycles over a specified period of time in either or both ventricles has dropped below a specified threshold value.
5. (Original) The device of claim 1 wherein the triggering condition is when the percent of paced cycles over a specified period of time in either or both ventricles has dropped below a specified threshold value within a particular rate range.

6. (Original) The device of claim 1 wherein the triggering condition is when the number of consecutive intrinsic beats has exceeded a specified threshold value.
7. (Original) The device of claim 1 wherein the triggering condition is when the number of times a pace has been inhibited by a synchronized-chamber protective period within a specified time interval has exceeded a specified limit value.
8. (Original) The device of claim 1 wherein the triggering condition is when the number of triggered paces in a specified time interval has exceeded a specified limit value.
9. (Currently Amended) The device of claim 1 wherein the controller is programmed to periodically measure the intrinsic PR interval by detecting the time interval between atrial and ventricular senses during unpaced beats, and wherein ~~the~~ an additional triggering condition is when the measured PR interval has deviated a defined percentage from a previously measured intrinsic PR interval.
10. (Original) The device of claim 1 wherein the particular sensing channel from which data is to be stored and whether the data is to be stored as an electrogram or marker/interval data depends upon detection of a particular triggering condition.
11. (Original) The device of claim 1 wherein data received from one or more selected sensing channels during a specified time immediately preceding detection of a triggering condition is stored in a memory upon detection of the triggering condition.
12. (Currently Amended) The device of claim 1 wherein ~~the~~ an additional triggering condition is when the delivered therapy is inconsistent with the programmed cardiac resynchronization therapy.
13. (Original) The device of claim 1 wherein the triggering condition is stored in a memory upon its detection.

14. (Currently Amended) The device of claim 1 wherein statistical data regarding ~~the~~ a triggering parameter is stored in a memory upon detection of a triggering condition.

15. (Original) The device of claim 1 wherein additional data regarding the physical condition of a patient in whom the device is implanted is stored in a memory upon detection of a triggering condition.

16. (Currently Amended) A method for operating a cardiac rhythm management device, comprising:

sensing cardiac electrical activity via a plurality of sensing channels;

outputting pacing pulses through plurality of pacing channels in order to pace both ventricles in accordance with a cardiac resynchronization pacing mode; and,

storing data received from one or more selected sensing channels in a memory upon detection of a triggering condition indicating ~~degradation of resynchronization therapy~~ a decrease in pacing frequency over a specified period of time.

17. (Original) The method of claim 16 wherein the stored data is an electrogram from the selected sensing channel.

18. (Original) The method of claim 16 wherein the stored data is marker/interval data reflecting sensing and pacing events in the selected sensing channel and time intervals therebetween.

19. (Original) The method of claim 16 wherein the triggering condition is when the percent of paced cycles over a specified period of time in either or both ventricles has dropped below a specified threshold value.

20. (Original) The method of claim 16 wherein the triggering condition is when the percent of paced cycles over a specified period of time in either or both ventricles has dropped below a specified threshold value within a particular rate range.

21. (Original) The method of claim 16 wherein the triggering condition is when the number of consecutive intrinsic beats has exceeded a specified threshold value.

22. (Original) The method of claim 16 wherein the triggering condition is when the number of times a pace has been inhibited by a synchronized-chamber protective period within a specified time interval has exceeded a specified limit value.

23. (Original) The method of claim 16 wherein the triggering condition is when the number of triggered paces in a specified time interval has exceeded a specified limit value.

24. (Currently Amended) The method of claim 16 further comprising periodically measuring the intrinsic PR interval by detecting the time interval between atrial and ventricular senses during unpaced beats, and wherein ~~the~~ an additional triggering condition is when the measured PR interval has deviated a defined percentage from a previously measured intrinsic PR interval.

25. (Original) The method of claim 16 wherein the particular sensing channel from which data is to be stored and whether the data is to be stored as an electrogram or marker/interval data depends upon detection of a particular triggering condition.

26. (Original) The method of claim 16 further comprising, upon detection of a triggering condition, storing in memory data received from one or more selected sensing channels during a specified time immediately preceding detection of the triggering condition.

27. (Currently Amended) The method of claim 16 wherein ~~the~~ an additional triggering condition is when the delivered therapy is inconsistent with the programmed cardiac resynchronization therapy.

28. (Original) The method of claim 16 further comprising storing the triggering condition in a memory upon its detection.

29. (Currently Amended) The method of claim 16 further comprising storing statistical data regarding ~~the~~ a triggering parameter in a memory upon detection of a triggering condition.

30. (Original) The method of claim 16 further comprising storing additional data regarding the physical condition of a patient in whom the device is implanted in a memory upon detection of a triggering condition.

31. (Original) The device of claim 1 wherein the data is stored for a specified storage time upon detection of a triggering condition.

32. (Original) The method of claim 16 wherein the data is stored for a specified storage time upon detection of a triggering condition.

33. (Original) The device of claim 1 wherein storage of data upon detection of a triggering condition is inhibited if a pathological condition is also detected.

34. (Currently Amended) The method of claim 16 further comprising inhibiting storage of data upon detection of a triggering condition if a pathological condition is also detected.

### **REMARKS**

This is in response to the Office Action mailed on July 15, 2004, and the references cited therewith.

Claims 1, 9, 12, 14, 16, 24, 27, 29, and 34 are amended herein. Claims 1-34 remain pending in this application.

#### **§103 Rejection of the Claims**

Claims 11 and 26 were rejected under 35 USC § 103(a) as being unpatentable over Vanderlinde et al. (U.S. Publication No. 2002/0082509) in view of Peterson (U.S. Patent No. 5,447,519). Claims 11 and 26 were rejected under 35 USC § 103(a) as being unpatentable over Stahmann et al. (U.S. Patent No. 6,480,742) in view of Peterson (U.S. Patent No. 5,447,519). Claims 11 and 26 were rejected under 35 USC § 103(a) as being unpatentable over Kramer et al. (U.S. Publication No. 2003/0060851) in view of Peterson (U.S. Patent No. 5,447,519). In view of the common ownership of the present application and the Vanderlinde et al., Stahmann et al., and Kramer et al. references as set forth below, applicant asserts that those references are not prior art to the present application for purposes of 35 U.S.C. 103. Reconsideration and withdrawal of the rejections based upon 35 U.S.C. 103 is therefore respectfully requested.

#### **Statement of Common Ownership**

Applicant declares that, at the time the present invention was made, the present application and Vanderlinde et al. (U.S. Publication No. 2002/0082509) were owned by the same entity. Applicant also declares that, at the time the present invention was made, the present application and Stahmann et al. (U.S. Patent No. 6,480,742) were owned by the same entity. Applicant also declares that, at the time the present invention was made, the present application and Kramer et al. (U.S. Publication No. 2003/0060851) were owned by the same entity. Since those patents or patent applications could only otherwise qualify as prior art to the present application under 35 U.S.C. 102(e), they are disqualified as prior art for purposes of section 103(a) under 35 U.S.C. 103(c).

§ 102 Rejection of the Claims

Claims 1-3 and 16-18 were rejected under 35 USC § 102(e) as being anticipated by Vanderlinde et al. (U.S. Publication No. 2002/0082509). Claims 1, 13-14, 16 and 28-29 were rejected under 35 USC § 102(e) as being anticipated by Stahmann et al. (U.S. Patent No. 6,480,742). Claims 1, 15-16 and 30-32 were rejected under 35 USC § 102(e) as being anticipated by Kramer et al. (U.S. Publication No. 2003/0060851). Claims 1 and 16 have been amended herein to recite a device and method, respectively, in which data received from one or more selected sensing channels is stored in a memory upon detection of a triggering condition indicating a decrease in pacing frequency over a specified period of time. Applicant does not find a teaching for this recitation in the cited references. The remaining claims rejected on this ground depend from either claim 1 or 16 and hence also incorporate the amended recitation. Applicant thus believes the section 102 rejections have been overcome.

Allowable Subject Matter

Claims 4-10, 12, 19-25, 27 and 33-34 were objected to as being dependent upon a rejected base claim, but were indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant believes that the amendments contained herein have rendered all of the pending claims allowable over the prior art of record.



Conclusion

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (847) 432-7302 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,


JEFFREY E. STAHMANN ET AL.

By their Representatives,

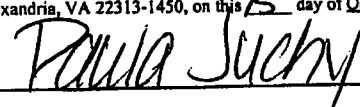
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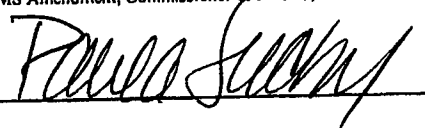
Date 10-15-04

By

  
J. Kevin Parker  
Reg. No. 33,024

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 15 day of October, 2004.

  
Name

  
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